

Attorney Docket No. B0801/7117

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

RECEPTOR SPECIFIC TRANSEPITHELIAL TRANSPORT OF THERAPEUTICS

the specification of which is attached hereto unless the following is checked:

[X] was filed on July 24, 1998, as United States Application No. 09/122,144 or PCT
(Include Series Code)
International Application No. _____, bearing attorney docket No.
B0801/7117, and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or section 365(a) of any PCT International application designating at least one country other than the United States listed below and have also identified below any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed:

Prior Foreign PCT International Application(s) and any priority claims under 35 U.S.C. §§119 and 365(a), (b):

(Number)	(Country-if PCT, so indicate)	(DD/MM/YY Filed)	Priority Claimed
			[] []
			YES NO
(Number)	(Country)	(DD/MM/YY Filed)	[] []
			YES NO
(Number)	(Country)	(DD/MM/YY Filed)	[] []
			YES NO

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(Application Number) (filing date)

(Application Number) (filing date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s), or §365(c) of any PCT International application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56

which became available between the filing date of the prior application and the national or PCT International filing date of this application:

<u>08/899,856</u> (Application No.)	<u>July 24, 1997</u> (filing date)	<u>Pending</u> (status-patented, pending, abandoned)
<u>08/578,171</u> (Application No.)	<u>December 29, 1995</u> (filing date)	<u>Pending</u> (status-patented, pending, abandoned)
<u>08/364,159</u> (Application No.)	<u>January 17, 1995</u> (filing date)	<u>Pending</u> (status-patented, pending, abandoned)

PCT International Applications designating the United States:

(PCT Appl. No.)	(U.S. Ser. No.)	(PCT filing date)	(status-patented, pending, abandoned)
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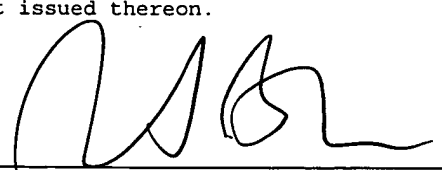
I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

David Wolf	17,528	James H. Morris	34,681	John R. Van Amsterdam	40,212
George L. Greenfield	17,756	Peter C. Lando	34,654	Matthew B. Lowrie	38,228
Stanley Sacks	19,900	Gary S. Engelson	35,128	Michael G. Verga	39,410
Edward F. Perlman	28,105	Peter J. Gordon	35,164	Robert E. Rigby, Jr.	36,904
Lawrence M. Green	29,384	Randy J. Pritzker	35,986	Robert A. Skrivaneck, Jr.	41,316
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Therese A. Hendricks	30,389	Douglas R. Wolf	36,971	Lesley A. Hamlin	41,054
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Ronald J. Kransdorf	20,004	John N. Anastasi	37,765	Michele J. Young	P-43,299
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James J. Foster	30,052	James M. Hanifin, Jr.	39,213	Alan B. Sherr	P-42,147
Charles E. Pfund	17,030	Christopher S. Schultz	37,929	John C. Gorecki	38,471
Jason M. Honeyman	31,624	Paul D. Sorkin	39,039	William G. Gosz	27,787

Address all telephone calls to Edward R. Gates at telephone no. (617) 720-3500. Address all correspondence to

Edward R. Gates
c/o Wolf, Greenfield & Sacks, P.C.,
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210-2211

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.


Inventor's signature
Full name of sole or first inventor Richard S. Blumberg
Citizenship US
Residence (City and State, or City and Country for non-U.S. residence)
34 Lagrange Street, Chestnut Hill, MA 02167
Post Office Address: same as above

12/8/98
Date

Inventor's signature

Date

Full name of second or joint inventor Neil E. Simister

Citizenship UK

Residence (City and State, or City and Country for non-U.S. residence)
19 Aron Road, Wellesley, MA 02181

Post Office Address: same as above

Inventor's signature

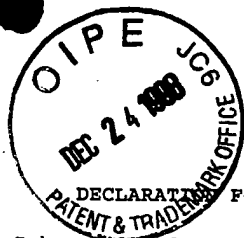
Date

Full name of sole or first inventor Wayne I. Lencer

Citizenship US

Residence (City and State, or City and Country for non-U.S. residence)
60 Louder Lane, Jamaica Plain, MA 02130

Post Office Address same as above



Attorney Docket No. B0801/7117

As a below named inventor, I hereby declare that:

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RECEPTOR SPECIFIC TRANSEPITHELIAL TRANSPORT OF THERAPEUTICS

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(Number)	(Country-if PCT, so indicate)	(DD/MM/YY Filed)	Priority Claimed
			<input type="checkbox"/> <input type="checkbox"/>
			YES NO
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			YES NO
(Number)	(Country)	(DD/MM/YY Filed)	<input type="checkbox"/> <input type="checkbox"/>
			YES NO

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(Application Number)	(filing date)
(Application Number)	(filing date)

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<u>(PCT Appl. No.)</u>	<u>(U.S. Ser. No.)</u>	<u>(PCT filing date)</u>	<u>(status-patented, pending, abandoned)</u>
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Inventor's signature _____ Date _____
Full name of sole or first inventor Richard S. Blumberg
Citizenship US
Residence (City and State, or City and Country for non-U.S. residence)
34 Lagrange Street, Chestnut Hill, MA 02167
Post Office Address: same as above

Neil E. Simister

12.7.98

Inventor's signature

Date

Full name of second or joint inventor Neil E. Simister

Citizenship UK

Residence (City and State, or City and Country for non-U.S. residence)
19 A~~y~~on Road, Wellesley, MA 02181

Post Office Address: same as above

Inventor's signature

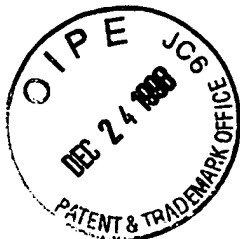
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Full name of sole or first inventor Wayne I. Lencer

Citizenship US

Residence (City and State, or City and Country for non-U.S. residence)
60 Louder Lane, Jamaica Plain, MA 02130

Post Office Address same as above



Atty. Docket No. B0801/7117 (ERG)

Applicant or Patentee: Blumberg et al.
Serial or Patent No.: 09/122,144
Filed or Issued: July 24, 1998
For: RECEPTOR SPECIFIC TRANSEPITHELIAL TRANSPORT OF
THERAPEUTICS

**DECLARATION CLAIMING SMALL ENTITY STATUS
(SMALL BUSINESS CONCERN)**

I hereby declare that I am an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: Epithelial Delivery, Inc.
ADDRESS OF CONCERN: 34 Arlington Street
Winchester, Massachusetts 01890

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled RECEPTOR SPECIFIC TRANSEPITHELIAL TRANSPORT OF THERAPEUTICS by inventor(s), Richard Blumberg et al., described in

- ☐ the specification filed herewith
☒ application serial no 09/122,144, filed July 24, 1998
☐ patent no. _____ issued _____

If the rights held by the small business concern are not exclusive, each individual concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(e) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

- ☐ no such person, concern, or organization
☐ persons, concerns or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

DEC 15 '98 12:38 FR

GREENFIELD SHACKS 5/17/1998

DEC 15 '98 13:28

which became available between the filing date of the prior application and the national or PCT International filing date of this application:

<u>08/511,816</u> (Application No.)	<u>July 24, 1997</u> (filing date)	<u>Pending</u> (status-patented, pending, abandoned)
<u>08/578,171</u> (Application No.)	<u>December 29, 1995</u> (filing date)	<u>Pending</u> (status-patented, pending, abandoned)
<u>08/359,159</u> (Application No.)	<u>January 17, 1995</u> (filing date)	<u>Pending</u> (status-patented, pending, abandoned)

PCT International Applications designating the United States:

(PCT Appl. No.)	(U.S. Ser. No.)	(PCT filing date)	(status-patented, pending, abandoned)
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Lawrence M. Green	29,384	Randy J. Britaker	35,986	Robert A. Skrivanek, Jr.	41,316
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M. Lawrence Oliverio	30,915	Helen C. Kindregan	39,248	Edward J. Russavage	P-43,059
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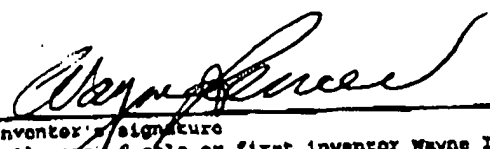
Edward R. Gates
c/o Wolf, Greenfield & Shacks, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02110-2311

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Inventor's signature _____ Date _____
Full name of sole or first inventor Richard S. Blumberg
Citizenship US
Residence (City and State, or City and Country for non-U.S. residence)
34 Lagrange Street, Chestnut Hill, MA 02167
Post Office Address: same as above

 Inventor's signature
 Full name of second or joint inventor Neil E. Simister
 Citizenship UK
 Residence (City and State, or City and Country for non-U.S. residence)
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 Post Office Address: same as above

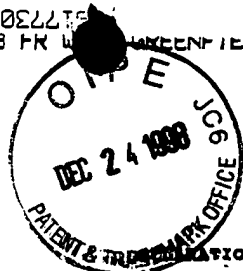
Date



 Inventor's signature
 Full name of sole or first inventor Wayne I. Lancer
 Citizenship US
 Residence (City and State, or City and Country for non-U.S. residence)
 60 Louder Lane, Jamaica Plain, MA 02130
 Post Office Address: same as above

Date

12/15/98



Attorney Docket No. B0801/7117

DECLARATION FOR PATENT APPLICATION

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My residence, post office address and citizenship are as stated below next to my name.

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RECEPTOR SPECIFIC TRANSEPITHELIAL TRANSPORT OF THERAPEUTICS

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☒ was filed on July 24, 1998, as United States Application No. 09/122,144 or PCT International Application No. _____, bearing attorney docket No. B0801/7117, and was amended on _____ (if applicable).

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Prior Foreign PCT International Application(s) and any priority claims under 35 U.S.C. §§119 and 365(a), (b):

			Priority Claimed	
			<input type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country-if PCT, so indicate)	(DD/MM/YY Filed)	YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(DD/MM/YY Filed)	YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(DD/MM/YY Filed)	YES	NO

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(Application Number) (filing date)

(Application Number) (filing date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s), or §165(c) of any PCT International application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56

U.S. Serial No. 09/122,144

Atty. Docket No. B0801/7117 (ERG)

FULL NAME Brandeis University
ADDRESS P.O. Box 9117, Waltham, MA 02254
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☒ NONPROFIT ORGANIZATION

FULL NAME The Brigham and Women's Hospital, Inc.
ADDRESS 75 Francis Street, Boston, MA 02215
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☒ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: Garen Bohlin
TITLE OF PERSON IF OTHER THAN OWNER: ~~Acting~~ President and Chief Executive Officer
ADDRESS OF PERSON SIGNING: Epithelial Delivery, Inc.
34 Arlington Street
Winchester, Massachusetts 01890

SIGNATURE Garen Bohlin DATE 11/20/98

218503.1

-2-

** TOTAL PAGE. 04 **



Attorney's Docket No. B0801/7117 (ERG)

Applicant or Patentee: Blumberg et al.
Serial or Patent No.: 09/122,144
Filed or Issued: July 24, 1998
For: RECEPTOR SPECIFIC TRANSEPITHELIAL TRANSPORT OF
THERAPEUTICS

**DECLARATION CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(e) and 1.27(d) - NONPROFIT ORGANIZATION)**

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF ORGANIZATION: Brandeis University
ADDRESS OF ORGANIZATION: PO Box 9117, Waltham, MA 02254

TYPE OF ORGANIZATION:

- ☐ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
☒ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) and 501(c) (3))
☐ NONPROFIT SCIENTIFIC OR EDUCATION UNDER STATUTE OR STATE OF THE UNITED STATES OF AMERICA
(NAME OF STATE)
(CITATION OF STATUTE)
☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) and 501(c) (3) IF LOCATED IN THE UNITED STATES OF AMERICA
☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATION UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
(NAME OF STATE)
(CITATION OF STATUTE)

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees under section 41 (a) and (b) of Title 35, United States Code with regard to the invention entitled RECEPTOR SPECIFIC TRANSEPITHELIAL TRANSPORT OF THERAPEUTICS by inventor(s), Blumberg et al., described in

- ☐ the specification filed herewith
☒ application serial no 09/122,144, filed July 24, 1998.
☐ patent no. _____, issued _____.

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above-identified invention.

If the rights held by the nonprofit organization are not exclusive, each individual concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

- ☐ no such person, concern, or organization
☒ persons, concerns or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME The Brigham and Women's Hospital, Inc.
ADDRESS 75 Francis Street, Boston, MA 02215
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☒ NONPROFIT ORGANIZATION

FULL NAME Epithelial Delivery, Inc.
ADDRESS 34 Arlington Street, Winchester, Massachusetts 01890
☐ INDIVIDUAL ☒ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

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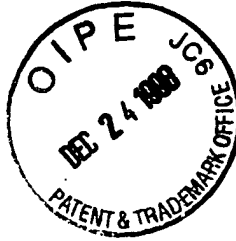
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NAME OF PERSON SIGNING: Sheryl Greenberg, Ph.D.

TITLE IN ORGANIZATION: Intellectual Property Manager

ADDRESS OF PERSON SIGNING: Brandeis University, PO Box 9117, 415 South Street, Waltham 02254
MA

Sheryl Greenberg 12/8/98
Signature Date



Atty. Docket No. B0801/7117 (ERG)

Applicant or Patentee: Blumberg et al.
Serial or Patent No.: 09/122,144
Filed or Issued: July 24, 1998
For: RECEPTOR SPECIFIC TRANSEPITHELIAL TRANSPORT OF THERAPEUTICS

**DECLARATION CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(e) and 1.27(d) - NONPROFIT ORGANIZATION)**

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF ORGANIZATION: The Brigham and Women's Hospital, Inc.
ADDRESS OF ORGANIZATION: 75 Francis Street
Boston, MA 02115

TYPE OF ORGANIZATION:

- ☐ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
☒ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) and 501(c) (3))]
☐ NONPROFIT SCIENTIFIC OR EDUCATION UNDER STATUTE OR STATE OF THE UNITED STATES OF AMERICA
(NAME OF STATE)
(CITATION OF STATUTE)
☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) and 501(c) (3) IF LOCATED IN THE UNITED STATES OF AMERICA
☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATION UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
(NAME OF STATE)
(CITATION OF STATUTE)

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees under section 41 (a) and (b) of Title 35, United States Code with regard to the invention entitled RECEPTOR SPECIFIC TRANSEPITHELIAL TRANSPORT OF THERAPEUTICS by inventor(s), Blumberg et al., described in

- ☐ the specification filed herewith
☒ application serial no 09/122,144, filed July 24, 1998.
☐ patent no. _____, issued _____.

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above-identified invention.

If the rights held by the nonprofit organization are not exclusive, each individual concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

- ☐ no such person, concern, or organization
☒ persons, concerns or organizations listed below*

U.S. Serial No. 09/122,144

Atty. Docket No. B0801/7117 (ERG)

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME Brandeis University
ADDRESS PO Box 9117, Waltham, Massachusetts 02254
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☒ NONPROFIT ORGANIZATION

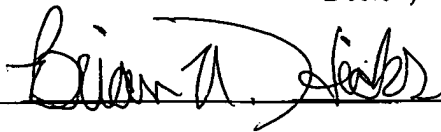
FULL NAME Epithelial Delivery, Inc.
ADDRESS 34 Arlington Street, Winchester, Massachusetts 01890
☐ INDIVIDUAL ☒ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: Brian Hicks
TITLE IN ORGANIZATION: Director, Ventures Department
ADDRESS OF PERSON SIGNING: The Brigham & Women's Hospital, Inc.
75 Francis Street,
Boston, MA 02115

SIGNATURE



DATE

11/20/98